Requirements for a monitoring sensor system to protect patients from vital threat

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Preface

This thesis is written as a final assignment for the bachelor Technical Medicine at the University of Twente. In this report, we will discuss the possibility of early detection of postoperative complications by means of a monitoring sensor system. We would like to thank our medical and technical supervisors prof. dr. M.M.R. Vollenbroek-Hutten, dr. ir. M.D.I. Lansbergen PDEng, M.C. Hermans MSc, and our tutor L. Wisse for their time and contribution. We would also like to thank all the doctors and nurses who have cooperated with our research. Finally, we would like to thank Henk Hofstede for his feedback concerning English and structure. Enjoy reading this thesis.
Abstract

Introduction. Insufficient frequency of measurements of vital signs causes too late detection of clinical deterioration which can lead to vital threat. A solution for this problem is a monitoring sensor system which can monitor patients in the hospital to help nurses to control patients from vital threat.

Study objective. The purpose of the monitoring sensor system is to prevent clinical deterioration by monitoring patients after high-risk gastrointestinal surgery and detecting complications early. The objective of the study is to determine requirements for a monitoring sensor system which is able to detect complications early to prevent vital threat.

Methods. This study was mainly done by research in literature. Next to this, nurses and doctors were interviewed to find out what the most important vital signs are and how these parameters change due to complications, what the practical requirements of a monitoring sensor system would be and how a gut feeling is established. Experiments were done on four healthy subjects to examine what the variation in vital parameters can be during walking, sitting and walking stairs. Technical requirements are drawn up and sensors are researched which can measure vital parameters. The requirements for implementing of this monitoring sensor system are researched. The ability to objectify ‘gut feeling’ is also researched.

Results. In the majority of complications after colon resection and esophagectomy, heart rate, respiratory rate and temperature change at first and the most. The complications with the highest risk of injury and death are pneumonia and anastomotic leakage. It is still unclear how the vital parameters change during the development of these complications. The experiments showed that baseline values of the vital parameters in rest differ between subjects. The increase of vital parameters differ too during activity. Furthermore, the threshold values obtained from Modified Early Warning Score (MEWS) as used in ZGT were exceeded during activity. Requirements of a monitoring sensor system are that it must be comfortable for the patient, easy to use for nurses, gives an alarm when values are abnormal and must show trends of the vital parameters. Possible sensors and multiparameter devices are given. Furthermore, risks of a system are alarm fatigue, abnormal vital signs can be missed because of a technical error and when using a network, cybersecurity is important. Gut feeling is important to quantify because this can detect vital deterioration earlier than changes in vital parameters occur. However, gut feeling is hard to objectify.

Discussion. A lot of further research has to be done. Which patients, for how long and when do they have to wear the device? What change in vital parameters is an indication for vital deterioration? To accomplish this, an algorithm should be made. Furthermore, other groups of patients at risk for vital treat should be researched to make the system applicable for them. Limitations of this study were the reliability of the used sensors during the experiments and the small-scale that was used for interviews, study population and experiments.

Conclusion. To detect complications with a monitoring sensor system early after colon resection and esophagectomy, the nurses should get an alarm if heart rate, respiratory rate and/or body temperature of patients reach threshold values. Before the monitoring sensor system can be developed and used in the hospital, the system needs all the requirements that were found. This study can be used as an overview for the development of a monitoring sensor system to prevent vital threat.
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1. Introduction

1.1 Context
The increase of older people causes more demand of healthcare. Namely, older people get ill more often than younger people. To meet this demand, healthcare must become more efficient. To be more efficient, people should stay at the hospital for a shorter time. This means that patients have to stay home longer if they get ill and that they will be dismissed from the hospital if staying is not absolutely necessary. This increases the average illness in hospital, which means that the number of patients in whom clinical deterioration occurs is higher and these patients have a higher chance on vital threat. The chance on vital threat also increases because complications are often detected too late. [Dr. E. Kouwenhoven, personal communication, 10-05-2017]

According to medical specialists from Ziekenhuis Groep Twente (ZGT), vital threat could have been prevented often by monitoring vital parameters more frequently. This frequent monitoring of patients is important because clinical deterioration can occur rapidly and this can result in permanent injury or death. [Dr. M. Lubbers, personal communication, 08-05-2017] [Dr. W. Nijmeijer, personal communication, 10-05-2017]

Currently, vital parameters are being measured once per shift of the nurses. This equals once per eight hours on average. The time between two measurements can rise to sixteen hours because some nurses perform measurements at the beginning of their shift and some nurses perform measurements at the end of their shift. However, changes in vital parameters can occur faster than this and as a result critical changes can be missed or can be detected too late. An increase of measurements during one shift could solve this problem but this would take too much time from nurses. Therefore, it is desirable that a monitoring sensor system is used to monitor patients more frequently. The first step in this development process is determining the requirements for a monitoring sensor system and how this system can predict vital threat. Therefore, this study will focus on setting requirements for a monitoring sensor system.

1.2 Patient monitoring
To detect clinical deterioration the Modified Early Warning Score (MEWS) is currently used in ZGT as an extra tool next to measurements of vital parameters of the patient and clinical observations. In theory, MEWS must be applied in every measurement but in practice it is mainly used when nurses have the feeling that something is wrong. However, blood pressure, heart rate, oxygen saturation and body temperature are parameters which are measured routinely. [Dr. M. Lubbers, personal communication, 08-05-2017] [Nurses surgery department, personal communication, 10-05-2017].

MEWS is based on six vital signs: respiratory rate, body temperature, systolic blood pressure, heart rate, alertness and urine production. When one of these values is increased or decreased and its threshold is exceeded, a score will be assigned. An extra point is given when the nurses are worried. All these scores are added and this will give the MEWS. Table 1.1 gives MEWS as used in ZGT. The higher the calculated score, the worse the health status of the patient. When a score of 3 is reached, the patient is threatened and a doctor has to assess the patient within 30 minutes. [1] [Dr. M. Lubbers, personal communication, 08-05-2017] When a score of five or higher is reached, there is an increased risk on admission to the intensive care unit or death of a patient. [2] At a score of 7 or higher, the doctor has to be reported immediately and has to set up a treatment plan to prevent the patient from deterioration. [1] [Dr. M. Lubbers, personal communication, 08-05-2017]. Gut feeling of the medical staff is also a sign to detect clinical deterioration. This feeling is often right but it is not objectively and hard to define. Gut feeling is a skill that doctors and nurses can develop through the years. [Dr. M. Lubbers, personal communication, 08-05-2017]

### Table 1.1: Modified Early Warning Score used in ZGT. [3] [Dr. M. Lubbers, personal communication, 08-05-2017]

<table>
<thead>
<tr>
<th>Systolic blood pressure (mmHg)</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;70</td>
<td>71-80</td>
<td>81-100</td>
<td>101-199</td>
<td>&gt;200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart rate (beats/minute)</td>
<td>&lt;40</td>
<td>41-50</td>
<td>51-100</td>
<td>101-110</td>
<td>111-129</td>
<td>&gt;130</td>
<td></td>
</tr>
<tr>
<td>Respiratory rate (beats/minute)</td>
<td>&lt;9</td>
<td>9-14</td>
<td>15-20</td>
<td>21-29</td>
<td>&gt;30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The different vital parameters are measured using certain methods in ZGT. Respiratory rate is measured by counting breaths per minute of the patient. It is important that the patient is distracted so the breathing is naturally and thus the measurement reliable. Heart rate is measured with a pulse oximeter, blood pressure is measured with a non-invasive electronic blood pressure monitor and temperature is measured with an ear thermometer. Level of consciousness is distinguished using different categories of consciousness: confused, responds to voices, responds to pain and no response. [Dr. M. Lubbers, personal communication, 08-05-2017] These methods are time consuming and therefore the vital parameters can not be measured often enough.

### 1.3 Study objectives

More frequent monitoring can possibly save patients with high risk on vital threat after gastrointestinal surgery. The choice for this group will be discussed in study population. [Dr. M. Lubbers, personal communication, 08-05-2017] [Dr. W. Nijmeijer, personal communication, 10-05-2017] Using the current method, most of the time vital threat is detected too late, which can cause aggravation of a postoperative complication. Nurses do not have enough time for extra measurements. Therefore, a monitoring sensor system, which can measure vital signs automatically, frequently and is mobile, can help the nurse to control their patients better. The purpose of the monitoring sensor system is to protect these patients from vital threat by early detection of changes in vital parameters. The objective of the study is to determine requirements for a monitoring sensor system which can detect complications early to prevent vital threat. Clinical knowledge will be combined with technical knowledge to research which techniques and algorithms are suited to solve the clinical problem. The objective of the study leads to the following research question: **What are the requirements of a monitoring sensor system for the early detection of complications after high-risk gastrointestinal surgery?**

To answer this question, different subquestions have to be researched. Which complications have to be detected, what vital signs and which change in these vital parameters have to be measured to detect the complications? After determining the vital signs, it is important to know whether a change in vital parameters is physiological or pathophysiological. These subjects will make clear what the new monitoring sensor system has to measure exactly. After this will be researched what kind of requirements are needed to make it able to measure vital deterioration and give an alert to the nurses if necessary. Future perspectives to measure gut feeling will be discussed in the last subquestion. This leads to the following subquestions:

1. **Which vital signs are relevant for early recognition of major complications after high-risk gastrointestinal surgery?**
2. **How do vital parameters progress in time during major postoperative complications?**
3. **What is the variation in vital parameters during daily life activity of hospitalized patients?**
4. **What are the technical requirements for a monitoring sensor system so it is clinically applicable?**
5. **What is needed for the objectification of gut feeling so it can be used in a monitoring sensor system?**

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>&lt;35</th>
<th>35-38,4</th>
<th>&gt;38,5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conscious level (AVPU-score)</td>
<td>Confused</td>
<td>Alert (A)</td>
<td>Responds to Voice</td>
</tr>
<tr>
<td>Urine production (mL/kg/hour)</td>
<td>&lt;0,5</td>
<td>&lt;1,0</td>
<td>Unknown</td>
</tr>
</tbody>
</table>
2. Method

Firstly, the study population will be described. Secondly will be described which information is needed to find answers of the subquestions and how this information will be gained. Each subquestion will be discussed and a conclusion will be drawn, which can be used in the next subquestions but will also be used to answer the main question. At last a final discussion and conclusion will summarize all requirements, give some proposals for further research and the clinical value of this research will be discussed.

2.1 Study population

This study has focussed on patients after high-risk gastrointestinal surgery in ZGT whose vital parameters are measured once in eight hours. This population is chosen because doctors said that this is a population where vital deterioration often develops in a short period of time. [Dr. M. Lubbers, personal communication, 08-05-2017] [Dr. E. Kouwenhoven, personal communication, 10-05-2017] Another reason was that the clinical state of the patients in this population is well known before surgery, which makes detecting change in vital parameters easier.

The high-risk gastrointestinal surgeries which are done in ZGT are: gastric bypass surgery, colon cancer surgery, gastric resection, esophagectomy and rectal cancer surgery [4].

Patients after high-risk surgery can develop several complications. Table 2.1 gives the most common complications after the six most common high-risk surgeries; pancreatectomy, esophagectomy, abdominal aortic aneurysm repair, coronary artery bypass grafting, aortic valve replacement, and mitral valve replacement.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Complication Incidence</th>
<th>Failure to Rescue</th>
</tr>
</thead>
<tbody>
<tr>
<td>All complications</td>
<td>Best: 32.7, Worst: 36.4</td>
<td>RR (95% CI): 1.11 (1.09-1.13)</td>
</tr>
<tr>
<td>Pulmonary failure</td>
<td>Best: 5.8, Worst: 9.0</td>
<td>RR (95% CI): 1.55 (1.49-1.62)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Best: 1.8, Worst: 2.2</td>
<td>RR (95% CI): 1.22 (1.13-1.33)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>Best: 4.5, Worst: 4.9</td>
<td>RR (95% CI): 1.09 (1.01-1.19)</td>
</tr>
<tr>
<td>DVT/PE</td>
<td>Best: 1.0, Worst: 0.9</td>
<td>RR (95% CI): 0.92 (0.81-1.03)</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>Best: 9.8, Worst: 11.5</td>
<td>RR (95% CI): 1.17 (1.13-1.22)</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>Best: 6.0, Worst: 5.8</td>
<td>RR (95% CI): 0.96 (0.85-1.08)</td>
</tr>
<tr>
<td>Surgical site infection</td>
<td>Best: 2.0, Worst: 1.8</td>
<td>RR (95% CI): 0.82 (0.85-1.01)</td>
</tr>
<tr>
<td>GI bleed</td>
<td>Best: 0.8, Worst: 1.1</td>
<td>RR (95% CI): 1.26 (1.11-1.42)</td>
</tr>
</tbody>
</table>

This study compared the complication incidence and the ‘failure to rescue’ between several hospitals. ‘Failure to rescue’ describes the percentage of the patients who died because of a postoperative complication but could have been prevented with adequate treatment. In conclusion, postoperative complications after high-risk surgeries can have fatal consequences which could have been prevented. (Table 2.1)

According to research in hospitals in the Netherlands there is a difference in failure to rescue rate between hospitals. [6] This indicates that dealing with complications is not always sufficient in some hospitals. Part of the solution can be early monitoring. This is confirmed by the doctors that were interviewed. [Dr. E. Kouwenhoven, personal communication, 10-05-2017] [Dr. W. Nijmeijer, personal communication, 10-05-2017]

Patients included in this study are not vital threatened because if they are, they are transferred to the medium or intensive care unit. Patients in medium and intensive care are excluded because their vital parameters are already measured continuously. Patients under 18 are also excluded because their vital parameters are different from adults.

2.2 Methods per subquestion

Subquestion 1: Which vital signs are relevant for early recognition of major complications after high-risk gastrointestinal surgery?

Morbidity, mortality and incidence of the high-risk gastrointestinal surgeries done in ZGT were searched in literature. The most important gastrointestinal surgeries are the surgeries with the highest estimated deaths due to postoperative complications. This was asked in interviews with medical staff. The combination of literature and interviews with
medical staff led to a choice for two important gastrointestinal surgeries for this study. By focussing on two surgeries the complications are known and the most important parameters can be determined. Furthermore, the origin of developing complications may vary per surgery and not every surgery can be researched because lack of time. Based on the postoperative complications of these surgeries was researched in literature which vital parameters change due to the complications. The choice for vital parameters is based on more complications than researched in subquestion two to make the system suitable for the detection of different complications. After this overview was made, the vital parameters which change most and are most important to measure were chosen to research in this study. To accomplish this, research was done in literature. Furthermore, interviews were done with medical staff from ZGT. The interviewed medical staff was: Dr. E.A. Kouwenhoven, gastrointestinal surgeon, Dr. M. Lubbers, doctor at the gastrointestinal surgery department, Dr. W. Nijmeijer, doctor at the surgery department, A. Visschedijk, head of the ambulatory department, nurses at the surgery department, J. Rozendom, nurse at the intensive care and. The interviews are elaborated in appendix A. These doctors and nurses were chosen because their information could be valuable for the study because patients will be measured continuously but they will not always be guarded, so an alarm should go off to warn a nurse. The nurses from the intensive care could give an indication for when an alarm should go off.

Subquestion 2: How do vital parameters progress in time during major postoperative complications?
Subquestion two discusses the changes in vital parameters caused by the complications with the highest risk of injury and death. At first, two complications which occur often and have a high risk of deterioration were chosen based on interviews (Appendix A). This was confirmed by literature based on mortality rate of the complications. After this, the onset and clinical presentation of these complications were researched in literature and interviews. (Appendix A) Finally, research was done in literature and it was discussed whether a combination of abnormal vital signs can be a better predictor than a single abnormal vital sign.

Subquestion 3: What is the variation in vital parameters during daily life activity of hospitalized patients?
To determine whether a patient has a complication, it is important to determine which vital parameters change if a complication occurs, as seen in subquestion 2. However, it is just as important to determine what the normal ranges of values of a patient are, otherwise it is unknown whether a change is abnormal. To do this, daily life activity of patients was described and after this, the variation in vital parameters during these activities is researched. The MEWS gives normal values in rest. However, if a patient will be monitored all day long, the values obtained from MEWS are less applicable because a patient is not in bed all day long. For example, patients go to the toilet, sit in a chair and sometimes go for a walk. Vital parameters will change as well because of these activities and it is not desirable that an alarm goes off if a patient becomes more active.

Therefore, a literature study to physiological ranges of vital parameters during certain activities is done and several experiments were done to determine what physiological changes occur due to daily life activities. In the experiments, healthy subjects followed a protocol with several daily life activities. The experiments were done with healthy subjects, to research if vital parameters can reach a MEWS threshold due to the activities in healthy subjects. If vital parameters of patients are measured, the vital parameters can change due to other unknown causes. To do experiments with patients to compare with healthy subjects, a METC request is needed, this would take too much time for this study. The experimental protocol can be seen in appendix B. The activities are lying on bed, walking, sitting on a chair, and walking stairs. During these activities, heart rate, breathing rate and body temperature were measured using sensors from the Experimental Centre for Technical Medicine (ECTM) at University of Twente.

The sensors that were used are seen in table 2.2. These sensors were the most suitable to measure vital parameters during activity available in the ECTM. The data of four subjects was measured during different activities. Three of the subjects were measured twice and one subject was measured once, due to a lack of time. During the activities, the subjects were wearing the E4 Empatica and SPIRE. The E4 Empatica is a wristband which measures heart rate (in beats per minute) derived from blood volume pulse measured by a photoplethysmography sensor. [7] The Empatica is a reliable method to measure heart rate [8]. The SPIRE is a wireless device which measures respiratory rate (in breaths per minute). It can be worn at the bra or the belt. The respiratory rate is derived from the contraction and expansion in the torso and diaphragm and is measured by activity and force sensors. [9] The reliability of the SPIRE is unknown however, this device is the only usable device to measure respiratory rate in ECTM. The ear thermometer was used to measure body temperature (in degrees Celsius). This is considered as a reliable method to measure body temperature. [10].
The data from E4 Empatica could be viewed and downloaded on the website of the producer. The data from SPIRE was obtained using the IOS application of the producer which was linked to the standard health application on iphone. The data from the ear thermometer was written down after each measurement. All this data was processed using MATLAB. The script used can be seen in Appendix C. A table was made of percentual changes of heart rate compared to the mean baseline during different activities. These percentual changes were calculated using MATLAB. Graphs of heart rate, respiratory rate and temperature were plotted against time. Different graphs for heart rate and respiratory rate with corresponding MEWS were made plotted against time. At last the added MEWS-points of heart rate and respiratory rate was plotted against time. The added MEWS-points were determined by determining the corresponding amount of points for every single measurement using table 1.1. These graphs were used to see whether there is a difference in range and baseline between persons. In addition to this, these graphs were used to see whether the values exceed the threshold of MEWS during daily activities.

<table>
<thead>
<tr>
<th>Sensor</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPIRE [9]</td>
<td>Respiratory rate</td>
</tr>
<tr>
<td>Ear thermometer</td>
<td>Body temperature</td>
</tr>
</tbody>
</table>

Subquestion 4: What are the technical requirements for a monitoring sensor system so it is clinically applicable?

After the determination of what functions should be measured, what changes should be detected and which complications should be detected early, additional requirements for application of the monitoring sensor system were set. These requirements were set based on interviews with medical staff of ZGT. These interviews were done to get an impression of the currently used method and the wishes for a new way of monitoring patients. Next to these requirements, additional requirements are determined by the research group.

When the requirements were clear, possible sensors for monitoring heart rate, respiratory rate and temperature were researched. After this, possibilities for a multiparameter monitoring system were considered. It is also important to think about how to deal with abnormal values. Therefore, the following questions were discussed: What are the threshold values for an alarm, how long can a value be abnormal for an alarm, what kind of alarm should be used, who should receive the alarm and how can the nurse react to the alarm?

In addition to meeting these requirements, the monitoring sensor system has to be implementable in a hospital. The medical technology department of ZGT was contacted to get to know what kind of requirements are needed for implementation. Finally, it was discussed which risks there could be at a sensor system and there was searched in literature what safety regulation should be applied to this medical technical device, so the system is implementable. Possible solutions to avoid these risks are discussed.

Subquestion 5: What is needed for the objectification of gut feeling so it can be used in a monitoring sensor system?

Besides vital parameters, gut feeling is an important factor for the determination of a patient’s well-being. Sometimes this can indicate a complication earlier than vital parameters do. At first, the importance of gut feeling according to nurses and doctors was described. Subsequently was searched for confirmation in literature. It is very difficult to determine what causes gut feeling exactly. To make this more clear it was researched in literature and with interviews how gut feeling can be defined and what could be indications for a gut feeling. Finally, possibly measurement methods of gut feeling were discussed. This subquestion was particularly an orienting research to look at future possibilities.
3. Results

3.1 Subquestion 1

Which vital signs are relevant for early recognition of major complications after high-risk gastrointestinal surgery?

High-risk gastrointestinal surgeries in ZGT

The mortality and morbidity rates of the high-risk gastrointestinal surgeries done in ZGT are researched to see which surgeries are defined as high-risk gastrointestinal surgery in this study. The incidence of the surgery is also important to take into account because the initial goal is to help as much patients as possible.

Table 3.1: High-risk gastrointestinal surgery with mortality and morbidity rate, incidence of surgery and possible complications.

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Mortality (%)</th>
<th>Morbidity (%)</th>
<th>Incidence of surgeries in 2015 in ZGT</th>
<th>Estimated deaths per year (incidence x mortality)</th>
</tr>
</thead>
</table>

Table 3.1 shows that the surgery with the highest morbidity and mortality rate is esophagectomy. The surgery with highest incidence is gastric bypass surgery but because the morbidity rate and mortality rate are very low, this surgery will not be chosen to be researched. The surgery with the second highest incidence is colon cancer resection. This surgery has also a high mortality rate.

This lead to the two most riskful gastrointestinal surgeries in ZGT: colon resections and esophagectomy. These surgeries are also the gastrointestinal surgeries which have the most estimated deaths. [Dr. E. Kouwenhoven, personal communication, 10-5-2017]

Indicators of postoperative complications

The complications which can occur after colon resection and esophagectomy are: (wound) infection, hemorrhage, thrombosis, pulmonary embolism, pneumonia, ileus, anastomotic leakage and heart and blood vessel disorders. [14-16]

Table 3.2 describes which vital signs change first after a complication occurs. An ‘x’ means that the function will not change primary after the complication occurred. For every complication is searched which vital signs change after a complication occurred. The vital signs which change with most complications are heart rate, blood pressure, respiratory rate, temperature and pain. Changes in saturation, diuresis and alertness occur less with these complications and are therefore not included in this study.

Postoperative ileus is not shown in table 3.2. The vital signs do not change directly with ileus, it could be diagnosed earlier by other symptoms. The symptoms of ileus are abdominal distension, vomiting, serious obstipation, lack of appetite and abdominal cramps. [17, 18] ‘Heart and vessel disorders’ is a general term, the most common heart or vessel disorder after gastrointestinal surgery is cardiac arrhythmia. This specific complication is shown in table 3.2. [19]

Doctors experience that the most important factors for recognizing clinical deterioration are respiratory rate and heart rate because these functions change first when a complication is present. Besides, doctors also check body temperature, to see if a complication is present because this is increased in case of infections. [20] [Dr. E. Kouwenhoven, personal communication, 10-05-2017] It is apparent from research that when there is impending clinical deterioration, there are subtle but significant changes in these functions. [21]
Table 3.2: First changes in vital signs after the most common complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Heart rate</th>
<th>Blood pressure</th>
<th>Saturation</th>
<th>Respiratory rate</th>
<th>Temperature</th>
<th>Alertness (AVPU)</th>
<th>Urine-production</th>
<th>Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Infection [22, 23]</td>
<td>Increase</td>
<td>Decrease in case of shock</td>
<td>x</td>
<td>Increase</td>
<td>Increase</td>
<td>x</td>
<td>x</td>
<td>Local pain</td>
</tr>
<tr>
<td>Hemorrhage [24]</td>
<td>Increase</td>
<td>Decrease</td>
<td>x</td>
<td>Increase</td>
<td>x</td>
<td>Decrease</td>
<td>Decrease</td>
<td>x</td>
</tr>
<tr>
<td>Thrombosis [18, 25]</td>
<td>x</td>
<td>Decrease</td>
<td>x</td>
<td>x</td>
<td>Slight increase</td>
<td>x</td>
<td>x</td>
<td>Local pain</td>
</tr>
<tr>
<td>Pulmonary embolism [18]</td>
<td>Irregular</td>
<td>x</td>
<td>Decrease</td>
<td>Increase</td>
<td>Slight increase</td>
<td>x</td>
<td>x</td>
<td>Pain on the chest</td>
</tr>
<tr>
<td>Pneumonia [20, 26]</td>
<td>Increase</td>
<td>x</td>
<td>Decrease</td>
<td>Increase</td>
<td>Increase</td>
<td>x</td>
<td>x</td>
<td>Pain during breathing</td>
</tr>
<tr>
<td>Anastomotic leakage [27]</td>
<td>Increase</td>
<td>Decrease</td>
<td>x</td>
<td>Increase</td>
<td>Increase</td>
<td>x</td>
<td>x</td>
<td>Pain</td>
</tr>
<tr>
<td>Arrhythmia [18]</td>
<td>Irregular</td>
<td>x</td>
<td>x</td>
<td>Increase</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Pain on chest</td>
</tr>
</tbody>
</table>

Discussion and conclusion
Next to heart rate, respiratory rate and temperature, there are other vital signs, like blood pressure and pain, which can give an indication for clinical deterioration. However, these functions are not researched because of the following reasons.

Changes in blood pressure often follow changes in heart rate and respiratory rate after a few hours. That is why blood pressure is a less important parameter. The goal after all is to recognize complications as early as possible. [28] [Dr. M. Lubbers, personal communication, 08-05-2017] Furthermore, the expectation is that blood pressure is difficult to measure with a sensor system.

Pain is an important factor to recognize complications but it is difficult to measure pain objectively. There have been some studies which tried but there is not a good way to do this yet. Further research has to be done before this can be applied. [29, 30] In addition, a patient will probably notify a nurse when he is in pain. Because of these reasons and the limited time, this will not be researched in this study.

In conclusion, this study is in first instance focused on heart rate, respiratory rate and temperature because these functions seem to be the best indication for vital deterioration.
3.2 Subquestion 2
How do vital parameters progress in time during major postoperative complications?

Complications with the highest risk of injury or death
Complications which are most important to detect early after esophagectomy and colon cancer resection are anastomotic leakage and pneumonia because these are the most common complications that can lead to vital deterioration. Early diagnosis should lead to a better treatment and can prevent vital threat. [6] [Dr. E. Kouwenhoven, personal communication, 10-5-2017] Patients with postoperative pneumonia after abdominal surgery have a ten times higher mortality rate than patients without pneumonia. Besides, patients have to stay on average ten days longer in hospital than patients who did not develop pneumonia. [31] Patients diagnosed with anastomotic leakage have a five times higher mortality rate than patients without anastomotic leakage. [32]

Onset of postoperative complications

Pneumonia
The risk of pneumonia is the highest in the first four days of hospital stay. When pneumonia occurs in the first four days after hospitalization or endotracheal intubation, it is called early-onset pneumonia. When it occurs after these first four days, it is called late-onset pneumonia. [33]

Anastomotic leakage
Anastomotic leakage after esophagectomy mostly appears between POD 4 and 8. [34] Colorectal anastomotic leakage develops most of the times between postoperative day (POD) three and five. [Dr. M. Lubbers, personal communication, 08-05-2017] Colorectal anastomotic leakage is usually detected between POD 5 and 8. [35]
There also has been a study which examined the differences between patients who were diagnosed with an anastomotic leak and patients without complications after bowel resection [27]. Figure 3.1, 3.2 and 3.3 show the differences between patients who develop an anastomotic leak in the first week after surgery (orange line) and patients without complications in the first postoperative week (green line). As you can see in figure 3.1, on POD 1 the green line decreases and the orange line increases. This means that relatively more patients with anastomotic leak have tachycardia (>100 bpm) directly after surgery. In figure 3.2, a difference is seen in the number of patients with tachypnea (>20 breaths per minute) of around 30 percent between patients with a known leak and patients without complications. In figure 3.3, the lines separate on POD 2, suddenly more patients with anastomotic leakage get fever (>38,0 °C) related to the other patients. With this information could be concluded that these three vital signs are more often increased in patients with anastomotic leak than in patients without complications. From the information from the graphs can be concluded that anastomotic leakage can develop from POD 1 or 2.
Clinical presentation of pneumonia
The edema in the alveoli causes a pulmonary shunt, so the alveoli will be perfused while there is no diffusion of oxygen and carbon dioxide in the alveoli. [36] To increase the ventilation, the respiratory rate has to increase. When the infection is severe, dyspnea could start in 2-3 days. [20] The heart rate will increase with the respiratory rate, to maintain the V/Q ratio by increasing perfusion. A few hours after the infection is present, the body temperature will rise due to inflammatory cytokines. These inflammatory cytokines are also responsible for the release of stress hormones. This leads subsequently to a rise in heart rate and breathing rate. [37, 38]

Literature does not give specific quantitative values for the abnormal parameters which develops in postoperative phase due to pneumonia. For early detection of pneumonia, it is important that research will be done to find out what the exact change of the vital parameters is and how the parameters progress during the first operative days.

Clinical presentation of anastomotic leakage
Anastomotic leakage will not directly lead to changes in vital signs. It can lead to infections such as peritonitis and abscess formation after colorectal anastomotic leakage and mediastinitis after esophagectomy, which all can lead to sepsis. [35, 39] These infections can lead to changes in vital signs. Mediastinitis and sepsis can lead to tachycardia. [18, 25, 40] Mediastinitis can lead to dyspnea, which will lead to tachypnea. Sepsis can also cause tachypnea. Peritonitis, abscess, mediastinitis and sepsis will all lead to fever. [18, 25, 40, 41] Though fever occurs in patients with and without mediastinitis, it is shown that patients with mediastinitis have a higher mean than patients without (38,3 °C vs 38,8 °C). [42] In the figures 3.1, 3.2, 3.3 is also seen that the vital signs change due anastomotic leakage. But this study does only take into account whether a value of a vital function is increased or decreased from a certain cut-off point (abnormal values were defined as body temperature >38°C, heart rate ≥100 bpm and respiratory rate ≥20 breaths per minute) and not the size of increase or decrease. It is possible that the values of patients with anastomotic leakage are much higher than the values of patients without. Values of the preoperative vital signs are also not taken into account, so maybe there is more change in patients with an anastomotic leak than in patients without complication. Quantitative values of

Figure 3.1: Percentage of patients with postoperative tachycardia (>100 bpm), comparison between patients with anastomotic leakage and patients without any complication. [27]

Figure 3.2: Percentage of patients with postoperative tachypnea (>20 breaths per minute), comparison between patients with anastomotic leakage and patients without any complication. [27]

Figure 3.3: Percentage of patients with postoperative fever (> 38,0 °C), comparison between patients with anastomotic leakage and patients without any complication. [27]
changes in vital parameters and development of these parameters during the first postoperative days due to anastomotic leakage are also not known in literature.

Discussion and conclusion

Tachycardia, tachypnea and fever are common changes after surgery in patients who develop a complication. But these changes also occur in patients with other complications or without complications at the same moment. The values of these changes are, as stated before, not known from literature. Combinations of these signs could be a more alarming sign. This is also seen in the MEWS, used in ZGT. A single abnormal vital sign will not always give a score of 3, which is the threshold for alarming a doctor but a combination of abnormal values can give this higher score. This means that a combination of vital signs can be more predictive for a complication than a single vital sign. However, the amount of research on this topic is very low. To get to know if a combination of values can be used, further research has to be done.

At the intensive care in the ZGT values are abnormal if they exceed a certain threshold. These thresholds are determined for every patient separately at the start of every shift because every patient has another baseline. This determination is also required for postoperative patients if a monitoring device is used in the future. If an abnormality in the values is shown, the nurse tries to determine if the abnormality is dangerous. For example, the abnormality can also be caused by eating or mobilizing. This judgement is made based on experience. [J. Rozendom, nurse intensive care ZGT, personal communication, 09-06-2017] This causes a problem for a monitoring device because a device gives an alarm based on data and tries to detect vital deterioration with algorithms. An algorithm, that takes trendlines into account, should be written for the monitoring device. Further research has to be done, to determine what else has to be taken into account for a reliable algorithm.

Pneumonia and anastomotic leakage are the most common complications that can lead to vital deterioration in the first week after gastrointestinal surgery. Pneumonia can be recognized by tachycardia, tachypnea or dyspnea and fever. Anastomotic leakage can be recognized by tachycardia, tachypnea and fever. Quantitative values of the changes which occur due to these complications are not found in literature. Combinations of vital parameters as predictor for complications are also not found in literature.

Exact values and combinations are not known. Therefore, MEWS, as used in ZGT, is used in subquestion three to determine what abnormal values of parameters are. MEWS is validated in literature as seen in the introduction. A combination of abnormal values, or a single high value should alarm the nurses to examine the patient. Further research has to be done to give specific values and possible combinations of values which can predict anastomotic leakage and pneumonia. Combinations of values might detect complications earlier than a value on his own.
3.3 Subquestion 3
What is the variation in vital parameters during daily life activity of hospitalized patients?

After the change in vital signs due to the complications is researched, it is important to know what the normal ranges of vital parameters are for patients without complications. Nowadays threshold values in rest are used for an indication for clinical deterioration but it is expected that vital parameters will also change due to activity. The vital parameters which will be discussed are heart rate, respiratory rate and body temperature.

**Physiology of vital signs**
To understand changes in vital parameters during movement, the physiology of the different vital signs is important.

**Heart frequency**
The heart rate is induced by the sympathetic nervous system and the parasympathetic nervous system. The heart rate will increase during activity via stimulation of the sympathetic nervous system, which is activated by adrenaline. On the other hand, the heart rate will be decreased in rest by released acetylcholine through stimulation of the parasympathetic system. A different amount of perfusion is needed during rest than during activities. The perfusion is regulated by the cardiac output, which is a product of the heart rate and stroke volume.

**Respiration**
Due to metabolism, there is a constant use of O2 and production of CO2 but the respiration keeps the levels of pCO2 and pO2 constant. Respiration is a combination of ventilation, diffusion of O2 and CO2 through the alveoli and perfusion of the bloodstream via pulmonary vessels.

**Body temperature**
The thermoregulatory system keeps the body temperature constant during changes of temperature in the environment or in the body. The regulatory system keeps a balance between heat production by metabolism and heat losses through the skin.

**Combination of vital signs**
All the three vital signs will be influenced by metabolism. Metabolism uses oxygen from the circulation and produces heat and carbon dioxide, where the respiratory rate will react on. The respiratory rate and heart rate are influencing each other by the ventilation/perfusion ratio. This ratio has to be constant, this means if the respiratory rate increases, the heart rate will increase too. When the respiratory rate is increased, the heat release will also increase due to loss of heat in breath. The increased heart rate needs more energy and therefore metabolism, so more heat will be produced. Increased heart rate and respiratory rate help with homeostasis of body temperature. [36]

**Daily life activity of patients**
Mobilization is important for a more favourable course of recovery. An example of a favourable effect of mobilization is that in upright position the vital capacity of a patient is higher than in lying position and proper ventilation is necessary to prevent pneumonia. Most common types of mobilization are sitting on a chair and walking. When a patient is feeling better, it is possible that the patient walks stairs. Even on the intensive care, patients have to mobilize if they are able to. [43] [Personal communication, nurses at the surgery department, 08-05-2017] [J. Rozendom, nurse intensive care ZGT, personal communication, 09-06-2017]

**Variation of vital parameters in rest according to literature**
In this study, lying position is defined as rest and baseline. The ranges of vital parameters in MEWS are based on patients in rest. The ranges of the heart rate, respiratory rate and temperature can be used in rest. These ranges will be validated by literature.

**Heart rate**
The normal heart rate according to MEWS is between 60-100 beats per minute, this is also validated in literature. [18] The heart rate can decrease till 40-50 bpm during sleep. [28]

**Respiratory rate**
The respiratory rate is according to MEWS normal between 9 and 14 breaths per minute. The physiological respiratory rates in adults differ in literature. Some say it is between 12 and 15 breaths per minute. [44] Another source says
between 12 and 20 breaths per minute and another says between 10-20 breaths per minute. [28, 45] Reasons for the different ranges in respiratory rate can be that respiratory rate depends on a lot of factors like age, population, body size and physical condition.

**Body temperature**
Following MEWS from ZGT, a temperature of 35 up to 38,4 °C can be normal. This is also validated in literature. [36, 46] The body temperature can vary about 1°C during the day, with a minimum between 3:00 am and 6:00 am of meanly 36,3°C and a maximum between 3:00 pm and 6:00 pm of meanly 37,3°C. [47]

**Variation of vital parameters while sitting according to literature**
When a patient sits, the expectation is that heart rate and temperature are the same as baseline. Furthermore, the respiratory rate can be lower because the tidal volume and vital capacity of the patient are increased.

**Variation of vital parameters while walking according to literature**

**Heart rate**
Due to the orthostatic response, the heart rate changes if a patient goes from lying to standing position. The autonomic nervous system mediates this response that raises heart rate. How much the heart rate increases depends on a variety of factors like total blood volume, temperature, initial heart rate and degree of tilt. [36] After thirty seconds of standing, the heart rate will be increased with 15-30% relative to the baseline. With a normal heart frequency in rest of 60-100 bpm, this is an increase of 9-30 beats per minute. [48, 49] The heart rate will also increase to increase the perfusion because the person needs more oxygen and produces more carbon dioxide during movement. Figure 3.4 below shows results of a study to differences in sensors to measure heart rate from 47 healthy adults. The sensors are appeared to be accurate and therefore the results can be used as reliable data. At rest, the heart rate is around 75 beats per minute. During walking it is increased up to 93 beats per minute, so this is an increase of about 25%.

**Respiratory rate**
Because of the increased activity, the metabolism has to increase to gain more energy. The patient needs more oxygen and produces more carbon dioxide, therefore respiratory rate will increase. The respiratory rate can also increase due to the increased heart rate.

**Body temperature**
The body temperature will remain approximately equal, due to thermoregulation. When more heat is produced by metabolism, the heat release will also increase. [36]

---

Figure 3.4: Mean heart rate by activity measured with different sensors. [50]

Figure 3.5: Changes in heart rate in ascending (triangles) and descending (squares) the stairs [51]
Variation of vital parameters while walking stairs according to literature

*Heart rate*
Walking stairs is more intensive than walking, so it is expected that the heart rate will increase more compared to walking. Following figure 3.4, the heart rate can increase with 100%, from 75 beats per minute in rest up to about 150 beats per minute while walking stairs. [50]
Another study focussed on changes in heart rate while ascending or descending stairs. As you can see in figure 3.5, in ascending stairs the heart rate rose to 159 beats per minute and in descending stairs, the heart rate rose to 107 beats per minute.
In conclusion, the heart rate during walking stairs can increase up to 159, which exceeds the threshold of MEWS.

*Respiratory rate*
Respiratory rate will increase more compared to walking because the person uses extra energy and therefore needs more oxygen. The exact value does not become clear from literature. Probably because it is difficult to measure during walking stairs.

*Body temperature*
As expected, body temperature will not change much while walking stairs because of homeostasis. [36]

Vital parameters after gastrointestinal surgery in patients without complications
Postoperative vital parameters can differ from preoperative vital parameters but this does not have to be an indication for a complication.
Medication can change heart rate, respiratory rate and body temperature. But these parameters can also change due to the effect of anaesthesia. In 12 hours after the surgery patients can have slight decrease in body temperature to 35 degrees Celsius. This effect is caused by anaesthesia or body heat loss during surgery. [52]
It is important to choose specific ranges of the parameters per patient. These ranges can be determined in the preoperative period. When this is done, abnormal changes can be seen in the postoperative phase.

Figure 3.6, shows that patients after bowel resection have abnormal vital signs while there is no complication present. Almost 60% - 70% of the patients has tachycardia during the first seven postoperative days and 60% of the patients has tachypnea during the first and seventh day.

![Figure 3.6: Graph of the incidence of abnormal vital signs by postoperative day in patients without complications. [27]](image)

Variation of vital parameters in daily life activity according to experiments
The initial purpose of the experiment was to investigate how vital parameters change during normal activities. The experiment protocol is described in the appendix.
As seen in figure 3.7, there is a wide range in values in different measurements of the heart rate during rest and activities. In table 3.3 is shown that change in heart rate due to activities, compared with baseline, also widely varies between subjects.
This applies for walking, sitting on a chair and walking the stairs. In rest, the heart rate lies between 60 and 100 bpm. It is difficult to determine whether a subject is vitally deteriorating if you look at values at one moment because values are very different per subject. For example, 90 bpm in rest can be a normal heart rate but if a patient’s normal heart rate in rest is 60 bpm, 90 bpm can be an indication for vital deterioration. Therefore, it is important look at the progression of heart rate in time instead of heart rate at one moment.

Table 3.3: Change of heart rate due to different activities.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Measurement</th>
<th>Mean heart rate baseline</th>
<th>Mean change due to walking</th>
<th>Mean change due to sitting</th>
<th>Mean change due to walking stairs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>63</td>
<td>24%</td>
<td>13%</td>
<td>55%</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>81</td>
<td>28%</td>
<td>16%</td>
<td>4%</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>95</td>
<td>11%</td>
<td>-10%</td>
<td>8%</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>73</td>
<td>30%</td>
<td>33%</td>
<td>32%</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>68</td>
<td>34%</td>
<td>9%</td>
<td>46%</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>64</td>
<td>46%</td>
<td>26%</td>
<td>no data</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>77</td>
<td>46%</td>
<td>-17%</td>
<td>46%</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>75</td>
<td>20%</td>
<td>9%</td>
<td>34%</td>
</tr>
</tbody>
</table>

Figure 3.7: Heart rate from 7 measurements of four different subjects during different activities. In the graph of the heart rate, different colours indicate different activities (green=lying on bed, blue=walking, yellow=sitting on a chair, red=walking the stairs)
Figure 3.8: Temperature from 7 measurements of four different subjects during different activities. The different colours indicate different activities (green=lying on bed, blue=walking, yellow=sitting on a chair, red=walking the stairs, orange=change between activities).

As seen in figure 3.8 the baseline value of the temperature also differs widely between 36.2 °C and 37.2 °C between different subjects. This means that for the temperature can be concluded as well that it is better to rely on changes instead of absolute values. This can be done by looking at trendlines. Another result that occurred from the experiment was that the temperature does not change significantly over time due to different activities.
In figure 3.9 is seen that there is also a wide variation in respiratory rate of different subjects during different activities. For example, a wide variation in baseline is visible between 14 and 21 breaths per minute. Another remarkable event is that one subject had the lowest respiratory rate during rest but had one of the highest respiratory rates during walking and walking the stairs (indicated by arrows in figure 3.9). This is once more an indication that there is a wide difference in respiratory rate between different persons.

![Figure 3.9: Respiratory rate from 7 measurements of four different subjects during different activities. The different colours indicate different activities (green=lying on bed, blue=walking, yellow=sitting on a chair, red=walking the stairs, orange=change between activities.](image)

**MEWS applied to experimental data**

To see if the MEWS is not only usable in rest but also during activities, the MEWS of heart rate and respiratory rate during different activities are shown in figure 3.10. The same graphs as figure 3.7 and figure 3.9 are shown but the colours now indicate the corresponding MEWS for that value of heart rate or respiratory rate. Body temperature is not pictured because in figure 3.8 is seen that in none of the measurements the body temperature exceeds the threshold values of MEWS. In the graphs in figure 3.10 can be seen that the MEWS in rest does not exceed the threshold for giving an alarm. Sometimes a MEWS of 1 is reached but this is not worrisome.
On the other hand, if a subject goes walking or walking stairs a higher MEWS is reached, which is alarming according to MEWS. This can also be seen in figure 3.11, where the added MEWS of heart rate and respiratory rate of one subject is displayed. In this figure it is shown that the subject almost all the time has a MEWS of at least 1, which is not worrisome. The MEWS goes up to 4 if the subject goes walking or walking the stairs.
Discussion and conclusion
The experiments show that every person has different threshold values and baselines for heart rate, respiratory rate and body temperature. The changes of heart rate due to activities widely varies between subjects as well. Therefore, these threshold values and baseline of vital parameters should be personalized. This can possibly be done by determining baseline values before surgery, so that these values can be set as baseline values. However, it is again important to keep in mind that every patient is in different condition, also before surgery. Sometimes this is visible in vital parameters and sometimes it is not. Obviously, if a patient is in bad condition but still scheduled for surgery, his preoperative values should not be set as baseline values.

According to literature, the normal ranges in heart rate and temperature in rest correspond with MEWS, however for respiratory rate different ranges are given. The upper threshold should possibly be raised to 20 breaths per minute but this requires further research.
The experiments show that heart rate and respiratory rate change due to activity as well. Body temperature does not change due to activity during the experiments. These results are in accordance with the literature. The extreme peaks in temperature are probably caused by measurement errors.
A more important fact about the change in heart rate and respiratory rate is that the parameters reached such a high value that they would give a MEWS of 4. This score would give an alarm if the guidelines of MEWS are used. Moreover, this score will possibly be even higher for patients in bad condition. In conclusion, in further research, threshold values of vital parameters during walking and climbing stairs have to be determined. The threshold values should change in case of activity of the patient. Therefore, the monitoring device should have a sensor that can notice activity.
3.4 Subquestion 4
What are the technical requirements for a monitoring sensor system so it is clinically applicable?

Practical requirements
The medical staff who is interviewed has several, mainly practical, requirements which can be seen in table 3.4. Next to this, additional requirements are determined based on ideas of the research group. To prioritise the requirements, the MoSCoW method is used. The MoSCoW method describes different categories for prioritising requirements. “Must have” means that the requirements must be taken into account because without these requirements the device will be not usable. “Should have” includes the requirements which are essential to take into account but without these requirements the system is still usable. “Could have” is also known as nice to have and is only taken into account when there is enough time. “Will not have” means that these requirements are not taken into account but in further research they can be interesting. [53]

Table 3.4: Requirements for the monitor device prioritised using MoSCoW method.

<table>
<thead>
<tr>
<th>Requirements for the monitoring sensor system according to medical staff</th>
<th>Must have</th>
<th>Should have</th>
<th>Could have</th>
<th>Will not have</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures heart rate, respiratory rate and body temperature continuously</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memory</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensors combined in one system</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Data readable on same device</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Wireless</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Comfortable to wear</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noninvasive</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy to put on and off or water resistant</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Easy to use for nurses</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Measures gut feeling</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Detects exercise</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Able to give an alarm</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

Additional requirements for the monitoring sensor system

| Validity                                                               | x         |             |            |              |
| Precision                                                             | x         |             |            |              |
| Cheap or reusable                                                     |           |             | x          |              |
| Trends of vital parameters visible directly                           |           |             | x          |              |
**Technical requirements according to medical staff**

The requirements are composed based on the interviews with medical staff. Deviating vital parameters can be an indication for a complication and should alarm the nurses. Not only deviating values are important but also changes in the vital parameters. The system should measure continuously, so trends in vital parameters will be clear. When continuous measurements are not possible, the desired frequency of measurements must be researched. To measure trends the system needs a memory so it can show changes over time. The memory should be deleted if the parameters did not change for a certain amount of time, to minimize the data storage and to keep it well-organized. The amount of time has to be determined by the nurses and doctors. A multiparameter sensor system contributes to the fact that it minimizes the inconvenience for the patient. Furthermore, the measurements should be readable on the same device. To minimize the inconvenience and because of the importance of mobilization for the patient’s recovery, it has to be mobile and wireless. Thereby the device should be water resistant, so the patient does not have to take off the device before taking a shower. If water resistance is not possible the device should be easy to put on and off. The device has to be easy to use for nurses because the new system should not take more time than the current method. It will not be a problem for nurses when the installation of the device needs extra time for the calibration of the system when the new system takes less time during monitoring. It is possible that nurses see clinical deterioration earlier based on gut feeling than on changes of vital parameters. Therefore, it would be great when a monitoring sensor system can measure gut feeling. Nowadays, gut feeling can not be measured with sensor technology. Until this is possible, nurses should still use their own gut feeling. Further research on this topic will be done in subquestion 5.

The monitoring sensor system must give an alarm when abnormal vital signs occur or when a vital parameter is changing in the direction of the threshold value. The abnormal values are discussed in subquestion three and will be used for threshold of an alarm further down in this chapter. [personal communication, Dr. Kouwenhoven, Dr. W. Nijmeijer, A. Visschedijck and J. Rozendom, Nurses surgery department, 10-05-2017]

**Additional technical requirements**

In addition to the requirements for the nurses and doctors, other technical requirements are needed for the new monitoring sensor system to be clinically applicable. The system should have a high validation and precision, so the measured values are reliable. The significance per sensor is based on the measured value. Temperature sensors have to measure little changes because the range of temperature is between 30–45 °C and the normal range is only 3°C. This means that a sensor should at least measure a difference with significance of ±0,05°C. The respiratory rate has also a little normal range between 9 and 14, however, the variation of respiratory rate is high, so a significance of ±0,25 is sufficient. In heart rate, a change of 1 bpm does not have much clinical value. Besides, the normal range is 50-100 bpm, so a significance of ±0,5 bpm is sufficient. The monitoring sensor system should have concurrent validity. This means that the measured values by the system are correlated with the values measured by the conventional measurement methods. Ideal should be that the system measures the same values. If the system measures values with a standard deviation compared with the conventional method, an algorithm should be used to calculate the right value. [54]

The monitoring sensor system will be used for every patient at high risk on vital threat, so it has to be cheap or reusable. A possible solution can also be that the monitoring sensor system is reusable and the attachment to the patient is replaceable. Trends in vital parameters must be seen directly in a graph with thresholds (figure 3.10), so the nurses can see easily if a threshold is exceeded by a single parameter and how long the parameter is changed.

**Sensor technology**

There are a lot of sensors available which can measure vital signs singly or can measure derivatives of vital signs, like pulse rate in correlation with heart rate. [55] In this part, possible sensors will be discussed per vital parameter using the requirements as determined before. The mechanism of the sensor, place on the body where it has to be used and how often the sensors can measure will be discussed.

**Heart rate**

There are a lot of possibilities for measuring heart rate. The two main mobile principles of measuring heart rate with sensor technology are electrocardiography and photoplethysmography.

**Electrocardiography (ECG)**

ECG is an accurate and reliable method for measuring heart rate variability. When monitoring with ECG, at least three electrodes must be used to measure the heart’s electrical activity. [56]
The electrodes detect changes in electrical signals from the heart which can be converted into a graph, also known as ECG wave. Heart rate can be determined from this information. Conventional ECG is not comfortable to wear because a lot of wires are needed to measure and convert the signal. Therefore, it would not be possible to use conventional ECG as a continuous monitoring device. On the other hand, ECG is a highly accurate method of measuring heart rate, also during activity. When, because of this reason, ECG will be chosen as a sensor for measuring heart rate, it must be a wireless ECG sensor. A commonly used mobile technique to measure heart rate continuously is a “Holter-monitor”[57]. As you can see in figure 3.12, a Holter-monitor can be used as a mobile measuring system. However, it has many wires and is not comfortable to wear for a long period. Besides the Holter-monitor, many commercial mobile ECG devices are being developed by several companies which are unfortunately not reliable enough to use in healthcare.

Figure 3.12: Example of a Holter-monitor[58]

Photoplethysmography (PPG)
Besides ECG, PPG can also be used to measure heart rate. PPG is often used in pulse oximeters and in wearable devices which are not used in healthcare. PPG can detect changes of the blood flow in, for example, the fingertip or the wrist. The heart rate can be derived from this information. Compared to ECG, PPG only measures heart rate, where ECG can measure the heart’s electrical activity as well. This study only focuses on heart rate, so PPG would be sufficient. Studies which compared the conventional method, ECG, with PPG conclude that PPG can be used accurately as a measuring method of heart rate in healthy persons in ideal conditions. With PPG it is possible to measure heart rate continuously, wirelessly and in a comfortable way but PPG is sensitive for motion artefacts and therefore it is not reliable enough to use for continuous monitoring in critically ill patients. [59]

Respiratory rate
Respiratory rate is a difficult vital sign to measure. The conventional method is counting the breaths seen by motion of the chest but it has been shown that this is not reliable. [60] Other reliable measurement methods are not favourable because these methods use a facemask, like capnography or an optical breath rate sensor. [61] Possible sensor methods which can be used in the monitoring sensor system are: Impedance pneumography, ECG-derived respiration, photoplethysmogram, inductive plethysmography and accelerometers.

Impedance pneumography (IP)
IP is the most commonly used respiratory rate sensor in hospitals. [62] This technique measures the impedance of the chest. This impedance changes during inhaling and exhaling due to the change in gas/fluid rate and the distance between the measure points. The impedance can be acquired using two electrodes but four electrodes give a more precise measurement. [63] However, it has errors due to motion or posture changes. [56] This is not desirable for a sensor system which should be worn all the time.

ECG-derived respiration (EDR)
A possible method to detect respiratory rate is EDR. There is a strong correlation between the respiration and the fluctuation in the mean cardiac electrical axis of the ECG caused by motion of the electrodes and changes in the electrical impedance due to inhaling and exhaling. By interpolating between axis measurements for each QRS top, an EDR signal is derived. It is possible to measure this with one ECG lead but it works best with two leads. [64] This can be measured with a normal ECG device as described earlier.
Photoplethysmogram (PPG)

PPG does not only measure heart rate, it is a possible method for detecting respiratory rate as well. The pressure in the chest is higher during inspiration than during expiration which causes the cardiac output slightly to increase or decrease due to respiration. This can be monitored anywhere on the skin where blood vessels are superficial. Unfortunately, this technique is sensitive to motion artefacts. [65]

Inductive plethysmography

Inductive plethysmography works placing one copper wire around the abdomen and another around the chest. Due to the volumetric differences in abdomen and chest during respiration, self-induction between the two wires occur. Inductive plethysmography is a more reliable technique to measure respiratory rate than IP because it is less prone to motion errors. [56]

Accelerometers

The accelerometer measures the inclination and angular changes of the torso during breathing. From this data, the respiratory rate can be derived with an algorithm. The device has to be worn with a band around the waist. It has an average error rate of 10%, which is too much for use in health care and it is not sensitive for movements of the patient. [66]

All these sensors can measure the respiratory rate continuously. IP and EDR has to be measured with electrodes, which could discomfort the patient. Inductive plethysmography and accelerometers have to be worn with a band, where inductive plethysmography does probably cause more discomfort than accelerometers because an accelerometer uses only one band, where inductive plethysmography uses two. In terms of comfort, PPG is probably the best sensor. However, it has been shown that EDR (95% LOA, -4.7 to 4.7 breaths per minute) is more precise than PPG (95% LOA, -5.1 to 7.2 breaths per minute) or IP (95% LOA, -5.6 to 5.2 breaths per minute). [62, 66]

Temperature

There are a lot of temperature sensors available but most of these sensors measure skin temperature. Skin temperature is always lower than core body temperature and is affected faster by environmental factors. When a temperature sensor is chosen, it is important that it measures body temperature. A continuous monitoring device which has to measure body temperature changes within a range of 33-43 degrees must be very accurate. Depending on the sensor which is chosen, the place on the body where it must measure the body temperature will be determined. Body temperature does not change fast, as seen in the results of the experiments in subquestion 3, it does not change while walking stairs or just lying in bed. Therefore, it is not needed to measure body temperature continuously. For example, twice per hour can be enough to detect complications but further research has to be done to define the exact frequency of body temperature measurements.

Sensors which can measure body temperature frequently and wirelessly and also are wearable and comfortable to use are hard to find nowadays.

Body temperature is measured with infrared technology most of the times but the measured temperature is strongly dependent on the way of measuring by infrared. Validated methods to measure core body temperature during rest and exercise are rectal measurements and an intestinal telemetric pill. Rectal measurements are not suitable because it is not comfortable at all to wear this continuously. An intestinal telemetric pill can be a possibility but can be seen as invasive because the patient has to swallow this pill.

After swallowing, the intestinal telemetric pill will pass the gastrointestinal tract based on the peristaltic motion. The intestinal telemetric pill has a verified accuracy of ±0.1 °C in a range of 35–45 °C. [67]

VitalSense is an example to measure body temperature wirelessly. Data can be immediately transmitted by radio telemetry with a minimum of every 15s to a wireless ambulatory chest strap that contains a variety of sensors. Then the collected data can be displayed and stored on a laptop via Bluetooth®. The VitalSense can provide an error but when it will be calibrated once with rectal temperature, it can give a reliable body temperature. [68] Another possible technique to measure temperature mobile is Zero-Heat-Flux thermometry (ZHF). [69-71] The temperature is measured by an insulator patch which is covered with an electric heater. Through the heat, skin surface convection stops and an isothermic tunnel will be formed between core body and skin surface. The heater and skin temperature become the same and the heat-flux is zero, the subdermal temperature can be measured 1 to 2 cm below skin surface. According to the research of M. Guschiibauer, the best place to measure temperature is near to the temporal corner of the eye [69].
The ZHF patch must be placed on a location with low skinfold thickness and a few large veins. Examples are: sternum, forehead and occipital region of the head. The patch must be flexible to prevent the occurrence of air between sensor and skin. [70]

Based on the amount of invasivity, ZHF seems the best appropriate method to use in a mobile sensor system.

Activity
As seen in subquestion 3, MEWS thresholds are not sufficient during movements of the patient. That is why it is important to use a sensor that can measure activity. When a patient becomes active, the sensor must detect this and adjust the threshold values to this activity. Sensors, which can detect activity, are discussed below.

Accelerometer
Accelerometers are sensors that measure the acceleration, and not the motion itself. When a patient walks, he probably walks in constant speed, due to which the forward motion is not visible on an accelerometer. However, a patient walks in a swinging rhythm, his hips and shoulders go up and down during walking, his hands and arms swing up and forth. These motions cause constant acceleration during walking, which can be measured with an accelerometer. [72] When a patient is being pushed around in a wheelchair or transferred in a bed, the accelerometer will shortly measure an acceleration but the patient sits or lays probably relatively still, which is why there will not be a constant acceleration.

Muscle activity
It is possible to attach an electromyography (EMG) sensor to a muscle, which a patient only or mostly uses during walking and other physical activities. There has been a study which developed and used a wireless and compact surface EMG sensor. This sensor could be useful because in this way, when a patient goes for a walk, the sensor can detect muscle activity and can pass down that the thresholds should change. The disadvantage of this method is that there is an extra measuring point because the other sensors will probably not be attached to such a muscle. [73]

Pedometer
The most accurate pedometer works by a horizontal spring suspended lever arm, which detects the vertical movement of the hip during walking. With each deflection, an electrical circuit opens and closes, which makes the total number of steps accumulate with one. This is a small, reliable and usable device. [72]

Multiparameter monitoring
The sensors described above only measure one of the three vital signs. The monitoring sensor system which can be used in hospitals should measure all the vital signs. Therefore, sensors must be combined. It is possible to search for a sensor which can measure the three vital signs on the same place of the body. For example, PPG can be used to measure heart rate and respiratory rate and a ZHF sensor which can measure the temperature of the blood on this place can be used to measure body temperature. But it is also possible to use several patches on different places of the body which communicate to one central system. There are a lot of possibilities to combine the sensors as described above.

Besides developing a new device, several multi parameters systems are already developed. Most of them do not exactly meet the requirements which are described above. Table 3.5 shows several promising multi parameter systems which partly meet the requirements described above. Advantages describes what the device already can measure following the requirements and disadvantages describes what is missing in the device. In most devices, skin temperature is measured. The devices need changes so that they meet the requirements from this study.

Table 3.5: Examples of multiparameter monitoring devices.

<table>
<thead>
<tr>
<th>Device</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>ViSi mobile</td>
<td>- Measures heart rate and respiratory rate.</td>
<td>- Does not measure body temperature</td>
</tr>
<tr>
<td></td>
<td>- Is mobile.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Already used in healthcare.</td>
<td></td>
</tr>
<tr>
<td>EarlySense</td>
<td>- Measures heart rate and respiratory rate.</td>
<td>- Not mobile</td>
</tr>
<tr>
<td></td>
<td>- Already used in health care.</td>
<td>- Does not measure body temperature</td>
</tr>
</tbody>
</table>
**MultiSense [76, 77]**
- Measures heart rate, respiratory rate and physical activity.
- Mobile and easy to wear.
- Does not measure body temperature.
- Only tested in in Sierra Leone.

**VitalPatch [78]**
- Measures heart rate, respiratory rate and activity.
- Does not measure body temperature.
- Not used in healthcare yet.

**Alarm**
When the three vital signs can be measured with a device, it is important to interpret the data which comes out of the device. When deterioration occurs, a sign must be sent to the nurses and action can be taken. The doctor will not get an alarm, communication about the patient will always be via the nurses. But which value is a sign for deterioration, how long may a value be deviated and which kind of alarms should be used? This will be discussed below.

**Threshold values**
MEWS can be used to determine threshold values in rest but as described in subquestion 3, threshold values may vary per person. Therefore, the threshold values have to be personalized. These threshold values must be measured in the preoperative phase or can be determined based on continuous measurements on the intensive care, if the patient went to the intensive care after surgery. The device should save this data and ranges. Postoperative vital parameters can be different compared to preoperative values but do not always have to indicate a complication. Furthermore, baseline values can differ during the recovery. Postoperative tachycardia does not have to indicate a complication for example but when the heart rate does not turn down to the preoperative baseline during recovery, the chance for a complication increases. On the intensive care, baseline values are evaluated by the nurse every start of a new shift. [J. Rozendom nurse intensive care ZGT, personal communication, 9-6-2017] This can be used in the postoperative department too.

In addition to the threshold values in rest, the baseline value and threshold values during activity should also be determined. The increase of vital parameters per activity can differ between patients because it depends on different factors, like condition, age and initial vital parameters. Baseline values during activity can be determined preoperatively by monitoring the patient while a longer time of walking or walking stairs. When measuring preoperative values is not possible, baseline values can be estimated based on expectations depending on literature or own experience.

**When alarm?**
Nurses on the intensive care in ZGT do get an alarm immediately if the threshold value is reached. [J. Rozendom nurse intensive care ZGT, personal communication, 9-6-2017] The patients on the intensive care are vital threatened or have much higher risk on vital deterioration compared to patients on the postoperative department. The nurses on the postoperative department are not focussed on the vital signs of patients all day, therefore, an alarm is needed when the patient needs further examination to detect vital deterioration and the possibility of complications. So, if a threshold is reached, it is not necessary that the nurses immediately get an alarm but they should only get an alarm when it is needed.

The time a deviating value may be present until an alarm rings depends on the quantity of the deviating value. If the vital parameter is far above the threshold values and has a MEWS of three, it is important to alarm earlier compared to a smaller deviation and a MEWS of one. In addition to pure values, increase of vital parameters is important too. When the vital parameters do not yet reach the threshold value but increases slowly in the direction of the threshold values, it can be an indication for the development of a complication. When values increase in a very short time, it is more likely caused by the patient getting up from bed or a measurement error than by a complication. Therefore, the monitoring sensor system has to sense increases or decreases of values and has to determine how fast these changes appear by using the steepness of the graph. In conclusion, the system is used on top of MEWS and uses MEWS thresholds for determining when to ring an alarm. So, it will be used as an extra tool to keep an eye on patients and the alarm will help nurses to decide whether extra measurements are needed to calculate a MEWS score.
Which alarm?
Different kind of alarms can be used to make a difference between life-threatening and less dangerous situations. The intensive care in ZGT uses three kinds of alarms with different kinds of sound and frequency, this is shown in table 3.6.

Table 3.6: Different alarms used at the intensive care [J. Rozendom nurse intensive care ZGT, personal communication, 9-6-2017]

<table>
<thead>
<tr>
<th>Colour of alarm</th>
<th>Reason for alarm</th>
<th>Kind of sound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Life-threatening danger</td>
<td>Loud, urging and fast</td>
</tr>
<tr>
<td>Yellow</td>
<td>Threshold is reached but not in a life-threatened region</td>
<td>Medium loud, medium frequency.</td>
</tr>
<tr>
<td>Blue</td>
<td>Technical problem</td>
<td>Short beeps with five seconds interval.</td>
</tr>
</tbody>
</table>

This system with three different kind of alarms can also be used for the new monitoring sensor system, apart from a few adjustments, as stated before. The exact cause for a specific alarm can be discussed with the nurses of the postoperative surgery, just like is done at intensive care. The different kind of alarms are needed to help the nurse with estimating the severity of the situation. In addition to these alarms, the patient should also still have the ability to call the nurse on his own.

Combination of threshold values, time and kind of alarm
After the threshold values of an alarm are determined, the time of deviation and kind of alarm, these indications for an alarm can be combined. How long a deviated value may be present until an alarm should ring also depends on how long one measurement will take. It is not desirable that an alarm is given, dependent on one measurement, which could also be a (technical) error. [Dr. Kouwenhoven, personal communication 10-05-2017] An example that can possibly be used is seen in table 3.7. However, this should be researched before these values can be used.

Table 3.7: Combination of MEWS score, time of deviation and alarm when every second a measurement is done.

<table>
<thead>
<tr>
<th>Score</th>
<th>Time</th>
<th>Kind of alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60 minutes</td>
<td>Orange</td>
</tr>
<tr>
<td>2</td>
<td>15 minutes</td>
<td>Orange</td>
</tr>
<tr>
<td>3</td>
<td>2 minutes</td>
<td>Orange</td>
</tr>
<tr>
<td>3</td>
<td>5 minutes</td>
<td>Red</td>
</tr>
<tr>
<td>4</td>
<td>10 seconds</td>
<td>Orange</td>
</tr>
<tr>
<td>4</td>
<td>1 minute</td>
<td>Red</td>
</tr>
<tr>
<td>5+</td>
<td>5 seconds</td>
<td>Red</td>
</tr>
</tbody>
</table>

To whom and reaction
The alarm will be send to the nurse who is responsible for the patient. The idea is that every nurse has a beeper system, with the size of a smartphone. The beeper shows three graphs with three different vital parameters, this will be showed in the big boxes. The current value will be showed in the little boxes, the box will light up if a value in that box is deviant. When an alarm is sent, the nurse can directly see how the vital parameters changed and can think of possible reasons for the changed parameters. On basis of this, the nurse can decide how to act. (figure 3.13)
When an alarm is given, the nurse can accept the alarm, which says that the nurse will react on the alarm. Another option is to delegate the alarm and the alarm will be send to another nurse, his or her ‘buddy’. When this nurse is not able to react soon, this nurse can also delegate the alarm, the alarm will be send to all the other nurses in the same department. If a nurse neglects the alarm, the loudness of the alarm will increase. [J. Rozendom nurse intensive care ZGT, personal communication, 9-6-2017] This ‘buddy system’ is used at intensive care in ZGT and is a concept that can be used in combination with the monitoring sensor system. However, it depends on the number of nurses, the size of department and the number of patients, how this concept can be used. It is not favourable that every alarm after delegated by two nurses, will be sent to the whole nurse team. It is possible to make a buddy system with, for example, four nurses who can delegate it to each other one by one.

All data of the sensors have to be saved in a small database and an algorithm must be developed to interpret the data. Following specialists in ZGT, they only want to get an alarm of abnormal vital signs when there is a complication present. It is a challenge to exclude all abnormalities which do not indicate a complication.

Risks of monitoring sensor system
Before the monitoring sensor system can be implemented, the risks have to be analysed to guarantee the quality for medical technology in the hospital. Before implementation in ZGT, the monitoring sensor system has to meet the requirements of QMT. [79] In addition to QMT, the Convenant has some requirements for implementation of a new medical system in a hospital in The Netherlands. A dossier should be made which contains: The necessity of acquisition, program of requirements of the hospital, a risk analysis, skill requirements of users and technicians and a periodic evaluation plan. Furthermore, it has to be assured that future users know how the device works and are competent to apply this. [80]

Next to the requirements, IGZ determined the opportunities should always be in balance with the risks and oversees if this is done correctly. [81]

A monitoring sensor system has various risks. A danger of a monitoring device which measures vital parameters and gives an alarm when these parameters are abnormal is that nurses will trust this device and will not check if the given parameters are correct. An abnormal vital sign which is missed because of an error in the alarming system or an error in threshold setting can have disastrous consequences. Because of this, it is very important that nurses exactly know how the device is working and that the device must be very accurate. The monitoring sensor system should give an alarm if repair is needed.

Too many warnings can also have consequences, it can lead to alarm fatigue. Experts say that alarm fatigue is the largest risk of alarm systems in healthcare. Too many alarms will lead to a less adequate reaction to abnormal signs and patient safety will decrease. Therefore, the sensor system must only give an alarm when relevant changes are present. [82]

Cybersecurity is important because the system will be wireless and so, a network will be necessary to communicate between several components of the system. Therefore, it is important to use a safe network.

Discussion and conclusion
Requirements according to medical staff are taken into account to determine requirements for a monitoring sensor system which can be implemented in hospitals. Possibilities of sensors are given and further research is needed to develop a multiparameter sensor system.
The alarm function is important to warn the medical staff when vital parameters are abnormal. An alarm must be given to the nurses when personalized thresholds are exceeded. The time that a value is abnormal must be researched because the system should only give an alarm when a complication is present. Furthermore, before a new medical system can be implemented, a dossier should be made which contains: The necessity of acquisition, program of requirements of the hospital, a risk analysis, skill requirements of users and technicians and a periodic evaluation. The information found in this chapter can be used as preconditions for the development of a monitoring sensor system.
3.5 Subquestion 5
Could gut feeling of nurses be monitored with sensors?

**Importance of gut feeling**
In addition to MEWS and measurements of vital parameters of the patient, intuition and gut feeling are increasingly accepted as indicators for the health of a patient. Experienced doctors and nurses can, often before changes in vital parameters occur, “see, feel or smell” when a patient deteriorates. However, this feeling is difficult to objectivate and it requires years of experience to obtain. When this feeling could be objectified, it is possible that a complication can be detected even before vital parameters change. Objectifying this feeling could also be helpful for the training of new nurses or doctors because in this way it will be more clear for nurses what signs are an indication of clinical deterioration. [Dr. E. Kouwenhoven, personal communication, 10-05-2017] In several researches it has been shown that the possibility to report a gut feeling is very important. There are many cases in which the nurse had a bad feeling about a patient but did not know exactly why and how to explain this. Therefore, it is important to listen to gut feeling and to research whether gut feeling could be validated and measured to detect vital deterioration earlier. [83, 84]

**Description of gut feeling**
A gut feeling is difficult to describe, however, general practitioners (GPs) have found consensus that a ‘sense of alarm’ means that they are concerned about a possible adverse outcome and worried about a patient’s health, even if there are no specific indications. This feeling activates the diagnostic process by considering hypotheses with a serious outcome. [85]
After research in literature and interviews, it turns out that there are some indications which could cause a gut feeling. It could be the colour of the patient, the amount of sweat or what the patient looks like. It could also be a comparison with patients they have seen before. [84] [Dr. E. Kouwenhoven, personal communication, 10-05-2017] A gut feeling could also be caused by new symptoms, a change in behaviour, a different look in the eyes, agitation of the patient or no progress when this is expected. [86]

**Quantifying gut feeling**
A possible way of measuring gut feeling is taking pictures of a patient or filming a patient and an algorithm could determine the illness of a patient. A mobile phone can already sort photos into different categories, a similar algorithm could be developed. This algorithm can, for example, be based on colour(change) and position. This algorithm could learn to recognize patterns. This way the algorithm learns from patients it has seen before and can recognize a complication earlier. Another possibility is measuring the amount of sweat or skin conductivity with a GSR sensor to see if a patient is deteriorating.

**Discussion and conclusion**
At the moment, it is not possible to measure gut feeling, mainly because it is unclear what causes a gut feeling. To discover what causes this feeling, it is important to do a prospective study where nurses will be asked what could be the cause of this feeling, when they say they have a gut feeling. With this information, it might be possible to draft an algorithm which can determine the illness of patient.
4. Discussion and study limitations

To detect complications early with a monitoring sensor system after colon resection and esophagectomy, the nurses should get an alarm if heart rate, respiratory rate and/or body temperature of patients reach threshold values. The threshold values have to be personalized and adjusted to activity. Before the monitoring sensor system can be developed and used in the hospital, the system needs all the requirements that were determined. However, there are several issues that should be discussed. Next to the things that were already mentioned, there are some other points which have to be researched before implementation.

One thing that must be researched is which patient have to wear the device. Is it desirable that all patients in a hospital are continuously monitored or should the device only be worn by patients that have high risk of vital deterioration but are not ill enough for the intensive care? To be suitable for all desired patients, more complications and surgeries have to be taken into account.

This leads to the next question: When and how long should patients wear this device? As researched in subquestion 2, pneumonia occurs most in the first four days of hospital stay and anastomotic leakage mostly occurs on POD 4 until POD 8. These results indicate that a monitoring sensor system for postoperative patients should be worn for at least 8 days. However, it is not known if other complications can occur after these 8 days. This should be researched before the system can be implemented.

The most important topic for further research is determining the way of measuring when a complication is developing. First, the types of sensors should be determined. If the sensors are chosen a study must be done to find out the combination of sensors and when the system must give an alarm. In this study was found that there is a wide variation between patients and activity leads to an exceed of thresholds that were used in MEWS. Therefore, MEWS can only be used to determine the threshold in rest for every parameter on his own. Not all parameters of MEWS are detected with the monitoring sensor system what can result in a MEWS which appears less high as it actually is. That is why it can be necessary to alarm before a score of three is reached.

To solve this, an algorithm should be made that notices vital deterioration because MEWS probably will not be sufficient. In order to make this algorithm there should be researched which bandwidth is normal for a patient and how thresholds can be determined for every patient. A promising way of determining a patient's condition is looking at the time it takes for the values of vital parameters to go back to baseline after activities. A good condition causes the vital parameters to return to the baseline faster compared with a worse condition. Personal thresholds could be determined this way. Parameters of patients with a worse condition will change more due to activity. The amount of time it takes for a patient’s parameters to go back to baseline can be an indicator for a patient’s recovery after surgery. Because the vital parameters will probably be elevated after surgery, a descending trend to baseline will be seen after surgery. If the values do not return to baseline, it can be an indication for vital threat.

To make the monitoring sensors system usable during activity there are several solutions. The first solution was discussed in subquestion 4, where several sensors that can measure activity were discussed. Another option to take activity into account is by looking at the slope of the different graphs. A change due to activity will give a steeper graph than a change due to a complication. However, to use this properly research must be done to determine how fast and how much vital parameters can change due to activity and due to complications.

Next to the patients after high-risk gastrointestinal surgery, there are two other groups of patients in ZGT where monitoring can be improved because deterioration is not always seen in time: Elderly patients of 70 years and older with cognitive distortion and patients on the emergency care department. These groups were not further researched because they were more complex than patients with gastrointestinal surgery. In the first group, elderly patients, delirium is the most common complication which can occur spontaneously. Fifteen percent of this group develops a delirium. [87] However, delirium is very difficult to notice with sensors, this is the main reason for not choosing this group.

The second group of patients are patients who arrive at emergency care department. In this stadium, the status of a patient is often unknown and because of this, a patient can deteriorate suddenly. A study to sudden deterioration on medical emergency department shows that 31% of the patients who arrive without any abnormal vital parameters, deteriorate within 24-hours. [88] This group was not chosen because it is very difficult to determine a complication if the status of the patient and possible complications is not known. In further research, these two groups and possible other groups must be taken into account as well to make the monitoring sensor system useful for all desired patients. For each group should be researched if the same parameters are important, how the patients mobilize, how the parameters change due to the most common complications within this group and if there should be other adjustments for these patients specifically.
A limitation of this study is the small scale which was used. As stated, there was only focussed on one group, two surgeries and two complications. When there would have been more time, more interviews with medical staff and in addition interviews with patients could have been done. This could have resulted in more insights on the requirements for the monitoring sensor system and possibilities for measuring gut feeling. Furthermore, new ideas could have been evaluated with the medical staff in a second interview. The small scale applies for the experiment as well. The experiments were done with only four healthy subjects. To get better results a larger group of healthy subjects should be examined as well as a group of patients. This was not possible in this study due to a lack of time.

Another limitation was the reliability of the SPIRE and ear thermometer. SPIRE is a consumer product and it is unclear how reliable this device is. However, the device did show the expected significant changes. Unfortunately, this was the only device which was available in the ECTM that could measure respiratory rate during walking activities. The sensitivity of the ear thermometer is relatively low (0.14-0.46 depending on cut-off value) but this the case with most noninvasive ear thermometers. The devices used in experiments were also not accurate enough to show direct changes in values due to change of activity. The respiratory rate and temperature were only measured once per minute. Although the heart rate was measured every second, the exact moment of change of activity could not be determined. An example how this can be done is inflicting a disturbance to the signal at the moment of changing activity. With this trick, the signals of different parameters can be aligned as well. This was not possible with our consumer sensors because we could not determine exactly how these devices worked.

If the experiment will be repeated, the protocol needs a few changes. In the figures 3.7, 3.8 and 3.9 is seen that the green line, which is baseline, is not always horizontal. Therefore, a trusty baseline value can not be determined. The baseline is most of the time affected by the activities before the baseline. If the experiment is repeated, the time for returning to baseline should be longer. This time should be determined depending on research to how long returning to baseline can take. However, this can differ per person because of physical condition. The kind of activities can be extended with other activities a patient can do, like going to the toilet or bending forwards. Furthermore, should be considered whether the activities are done long enough, a patient can also walk for more than five minutes. A longer period of measuring an activity is essential for the determination of normal values for this activity otherwise the values are influenced by other activities.
5. Conclusion

For the development of a monitoring sensor system that can prevent injuries and death by measuring vital parameters more often, several requirements are determined but further research has to be done. The monitoring sensor system should measure heart rate, respiratory rate and temperature because these parameters change due to the most complications caused by gastrointestinal surgery. Anastomotic leakage and pneumonia are complications which are most important to detect early after esophagectomy and colon resection. However, due to lack of information about specific changes in vital parameters, MEWS is used as threshold values in rest which can indicate clinical deterioration. When it is more clear at which time specific changes occur in these complications, it would be possible to detect clinical deterioration ever earlier. The threshold values should be adjusted in activity. The research done to the change in vital parameters due to complications and activity can be used in further research to determine when a nurse has to be warned by using algorithms. Technical requirements and safety requirements have to be taken into account, so that the monitoring sensor system is implementable in the hospital. The gut feeling could be measurable objectively in the future but this will take some time. The information gained in this study can be used as an overview in the further development of a monitoring sensor system to prevent vital threat.
6. References

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17. Beers, M.H., Merck Manual Medisch handboek. 2003, Bohn Stafleu van Loghum: Houten. p. 151-155; 165-168; 210-211; 246; 286; 325-327; 785-793 836; 1662-1665; 1715;.
27. van Loghum: Houten. p. 151-155; 165-168; 210-211; 246; 286; 325-327; 785-793 836; 1662-1665; 1715;.
Appendix

A. Interviews

Interview met arts-assistent Merel Lubbers op 8 mei.

- Algemene vragen:
  - Waar houdt u zich op dit moment mee bezig in het ziekenhuis?
  - Hoelang bent u werkzaam op dit gebied?
- Over de vitale functies:
  - Denkt u dat het nuttig is om de vitale functies vaker te monitoren?
    - Zo ja, hoe vaak ongeveer?
  - Hoe worden de vitale functies momenteel gemeten?
    - In hoeverre kijken jullie naar zuurstofsaturatie en diurese?
- Bij verslechterende patiënten:
  - Wat is de voornaamste reden voor verpleegkundigen om u naar een patiënt te roepen?
  - Wat is het eerste waar u naar kijkt als u naar een patiënt geroepen wordt?
  - Welke parameters zijn het belangrijkste voor een indicatie dat het echt heel slecht met een patiënt gaat?
  - Van welke vitale functies treedt snelle verandering op?
  - Wat zijn eventuele vervolgstappen?
- Specifiek over postoperatieve patiënten:
  - Wat verstaan jullie onder hoog-risico operaties?
    - Wij hebben gevonden: pancreatectomie, oesofagectomie, inbrengen bloedvatprothese bij herstel van een abdominale aorta aneurysma, plaatsing van een coronaire arterie bypass, aortaklepvervanging en mitralisklepvervanging.
  - Hoe lang na een operatie kunnen er complicaties optreden? Hoe lang is het dan belangrijk om continu te monitoren?
  - Hoe constateren jullie op dit moment complicatie? Is dit op tijd?
  - Bij welke complicaties is snelle behandeling van groot belang?
- Over de nieuwe techniek:
  - Wat zijn eisen aan een nieuwe techniek voor monitoring?

Interview met chirurg dr. E. Kouwenhoven op 10 mei.

- Algemeen:
  - Waar houdt u zich op dit moment mee bezig in het ziekenhuis?
- Specifiek over de opdracht:
  - We hoorden van Miriam Vollenbroek dat u een aandeel heeft gehad in het opzetten van dit onderzoek, kunt u een voorbeeld geven wanneer u dacht dat het vaker monitoren noodzakelijk is?
  - Wat zijn eisen aan een nieuwe techniek voor monitoring?
- Over de vitale functies:
  - Hoe vaak zouden de vitale functies gemonitord moeten worden?
  - Van welke vitale functies treedt snelle verandering op?
  - Op dit moment worden de vitale functies met MEWS gemeten, wat vindt u van deze methode?
  - Is continu monitoren van ademfrequentie, hartfrequentie en temperatuur genoeg voor het op tijd opmerken van complicaties?
    - Zouden bloeddruk, zuurstofsaturatie en diurese van belangrijke toegevoegde waarde zijn?
- Specifiek over de doelgroep vitaal bedreigde patiënten na hoog-risico operatie:
  - Wat verstaan jullie onder hoog-risico operaties?
    - Wij hebben gevonden: pancreatectomie, oesofagectomie, inbrengen bloedvatprothese bij herstel van een abdominale aorta aneurysma, plaatsing van een coronaire arterie bypass, aortaklepvervanging en mitralisklepvervanging, klopt dit?
  - Welke complicaties treden vaak op?
  - Hoe lang na een operatie kunnen er complicaties optreden?
    - Hoe lang is het dan belangrijk om te monitoren?
lijst van complicaties is snelle behandeling van groot belang?
- Waarop wordt de keus gebaseerd of de patiënt na een operatie naar de IC of direct naar de afdeling?
- Kun u tijdens de operaties bepaalde complicaties voorspellen?
- Hoe constateren jullie op dit moment een complicatie? Is dit op tijd?
- Welke parameters zijn het belangrijkst als indicatie dat het echt heel slecht met een patiënt gaat?
- Waar komt het ‘niet-pluisgevoel’ vandaan?

• Bij verslechterende patiënten:
  - Wordt u ook door verpleegkundigen naar de patiënt geroepen? En zo ja, wanneer?
  - Wat is het eerste waar u naar kijkt als u naar een patiënt geroepen wordt? Wat zijn eventuele vervolgstappen?

Interview met arts-assistent Wieke Nijmeijer op 10 mei

- Algemene vragen:
  - Waar houdt u zich op dit moment mee bezig in het ziekenhuis?
  - Hoelang bent u werkzaam op dit gebied?

- Over de vitale functies:
  - Op dit moment worden de vitale functies met MEWS gemeten, wat vindt u van deze methode?
  - Is continu monitoren van ademfrequentie, hartfrequentie en temperatuur genoeg voor het op tijd opmerken van complicaties?
    - Zouden bloeddruk, zuurstofsaturatie en diureese van belangrijke toegevoegde waarde zijn?
  - Van welke vitale functies treedt snelle verandering op?
  - Denkt u dat het nuttig is om de vitale functies vaker te monitoren?
    - Zo ja, hoe vaak ongeveer?

- Specifiek over de doelgroep vitaal bedreigde patiënten na hoog-risico operatie:
  - Wat verstaan jullie onder hoog-risico operaties?
    - Wij hebben gevonden: pancreatectomie, oesofagectomie, inbrengen bloedvatprothese bij herstel van een abdominale aorta aneurysma, plaatsing van een coronaire arterie bypass, aortaklepvervanging en mitralisklepvervanging, klopt dit?

  - Wanneer is een patiënt vitaal bedreigd?
  - Welke complicaties treden vaak op?
  - Bij welke complicaties is snelle behandeling van groot belang?
  - Wat zijn eventuele vervolgstappen?
  - Hoe lang na een operatie kunnen er complicaties optreden?
    - Hoe lang is het dan belangrijk om continu te monitoren?
  - Hoe constateren jullie op dit moment complicatie? Is dit op tijd?

- Bij verslechterende patiënten:
  - Welke parameters zijn het belangrijkst voor een indicatie dat het echt heel slecht met een patiënt gaat?
  - Wat is de voornaamste reden voor verpleegkundigen om u naar een patiënt te roepen?
  - Wat is het eerste waar u naar kijkt als u naar een patiënt geroepen wordt?
  - Kun u een beschrijving geven voor het ‘niet-pluisgevoel’?

- Over geriatrische patiënten:
  - Wat kunnen oorzaken zijn van een delier? Wat zijn de gevolgen?
  - Kan je het naast verwardheid ook merken aan vitale functies?
  - Zijn er naast delier ook andere ziektes die vaker voorkomen bij ouderen?

- Over de nieuwe techniek:
  - Wat zijn eisen aan een nieuwe techniek voor monitoring?

Interview met verpleegkundigen van de chirurgie en het unithoofd van het Ambulatorium op 10 mei.

- Algemene vragen:
  - Waar houdt u zich op dit moment mee bezig in het ziekenhuis?
  - Hoelang bent u werkzaam op dit gebied?

- Specifiek over vitale functies
  - Hoe worden de vitale functies momenteel gemeten?
Meet u altijd met MEWS?
Welke vitale functies meten jullie precies?
Is dit in elk ziekenhuis hetzelfde?
In hoeverre kijken jullie naar zuurstofsaturatie en diurese?
Denkt u dat het nuttig is om de vitale functies vaker te monitoren?
Zo ja, hoe vaak ongeveer?
Van welke vitale functies ziet u snelle verandering optreden?

Over de doelgroep: patiënten na een hoog-risico operatie
Wat verstaat u onder hoog-risico operaties?
Wanneer komen de patiënten direct naar de afdeling in plaats van IC?
Waarin gaan patiënten snel achteruit?
Wanneer heeft u een slecht voorgevoel bij een patiënt?
Waar komt het ‘niet-pluisgevoel’ vandaan?
Wat is de voornaamste reden voor u om een arts bij een patiënt te roepen?
Gebeurt dit vooral naar aanleiding van MEWS of ook op eigen initiatief?
Welke complicaties treden vaak op en moeten eerder opgemerkt worden?

Over het monitoren:
Denkt u dat de parameters uit MEWS het belangrijkste zijn? Welke parameters zijn essentieel, zullen bijvoorbeeld hartfrequentie, ademfrequentie en temperatuur genoeg zijn?
Wat zijn eisen aan een monitortechniek? (Bijvoorbeeld mobiel, gebruiksgemak, hoeveel tijd het mag kosten)

Specifiek voor de verpleegkundige van het ambulatorium:
Hoe lang verblijven patiënten hier en hoe vaak worden ze gemonitord?
Is continu monitoring hier dan echt van toegevoegde waarde?

Interview Intensive Care
Algemene vragen:
Waar houdt u zich op dit moment mee bezig in het ziekenhuis?

Over de vitale functies:
Wordt er op de intensive care ook met MEWS gewerkt?
Welke parameters worden continu gemeten?
Zou continu monitoren van alleen ademfrequentie, hartfrequentie en temperatuur genoeg voor het op tijd opmerken van complicaties?
Zouden bloeddruk, zuurstofsaturatie en diurese van belangrijke toegevoegde waarde zijn?
Van welke vitale functies treedt snelle verandering op?
Hoe reageert u bij verandering van vitale functies?

Bij verslechterende patiënten:
Welke parameters zijn het belangrijkste voor een indicatie dat het echt heel slecht met een patiënt gaat?
Wat is de voornaamste reden voor verpleegkundigen om u naar een patiënt te roepen?
Wat is het eerste waar u naar kijkt als u naar een patiënt geroepen wordt?
Kunt u het niet-pluisgevoel beschrijven?
B. Experimental protocol

**Purpose of the experiment:**
Changes in vital parameters during daily life will be determined to see whether an activity can lead to critical changes while no complication is present. This is important because a change in vital parameters must be measured with sensors and only give an alarm when thresholds are passed due to a complication.

**Materials:**
- E4 Empatica
- SPIRE
- Ear thermometer

**Methods:**
To measure heart rate, respiratory rate and body temperature, the 3 devices are used:
E4 Empatica is a wristband (worn on the left wrist) which will be used to measure heart rate in beats per minute. SPIRE will be used to measure respiratory rate and can be used on the belt in men and on the bra in women. It measures respiratory rate in breaths per minute.
Ear thermometer is used to measure body temperature in degrees Celsius (°C). E4 Empatica and SPIRE will be used during the whole experiment and the ear thermometer is used every minute, starting after 30 seconds. 4 subjects are used for the measurements. They are all measured 2 times following the same protocol. After every activity the subject has to lie down, so that the vital parameters can return to baseline. The results of the experiment will be processed in MATLAB.

**Protocol**
- Lying down (baseline): 3 minutes
- Walking: 5 minutes
- Lying down: 3 minutes
- Sitting: 5 minutes
- Lying down: 3 minutes
- Walking to the stairs: 30-60 seconds
- Walking stairs (ascending and descending): 2 minutes
- Walking back: 30-60 seconds
- Lying down: 3 minutes

**Subjects:**
Subjects which participated in this experiment are shown in table B.1:

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>Physical status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>male</td>
<td>21</td>
<td>184</td>
<td>74</td>
<td>healthy</td>
</tr>
<tr>
<td>2</td>
<td>female</td>
<td>21</td>
<td>165</td>
<td>67</td>
<td>healthy</td>
</tr>
<tr>
<td>3</td>
<td>male</td>
<td>22</td>
<td>195</td>
<td>80</td>
<td>healthy</td>
</tr>
<tr>
<td>4</td>
<td>female</td>
<td>21</td>
<td>164</td>
<td>60</td>
<td>healthy</td>
</tr>
</tbody>
</table>
C. MATLAB

% script voor het verwerken van de data van het experiment

tic
close all
clear all

tabelmaxHR = zeros(8,9);
tabelminHR = zeros(8,9);
for i = 1:7 % hiermee kunnen de metingen die afgebeeld moeten worden gekozen
    worden 1: subject1(4) 2: subject2(4) 3: subject3(4) 4: subject4(4) 5: subject4(5)
    6: subject2(5) 7: subject3(5) 8: subject1(5)
tic
    if i==1
        %INGEVOERD
        %subject1(4)
        colorbars = [1 0.5 0];
        run data4.m
        emp = empssubject1;
        spire = spiressubject1;
        temp = tempssubject1;
        trust1 = [93:274];
        tlopen1 = [274:573];
        trust2 = [573:754];
        tzitten = [754:1055];
        trust3 = [1055:1233];
        tlopen2 = [1233:1294];
        ttrap = [1294:1406];
        tlopen3 = [1406:1466];
        trust4 = [1466:1642];
    elseif i==2
        %Subject2(4)
        run data4.m
        emp = empssubject2;
        temp = tempssubject2;
        spire = spiressubject2;
        trust1 = [21:207];
        tlopen1 = [207:510];
        trust2 = [510:682];
        tzitten = [682:982];
        trust3 = [982:1162];
        tlopen2 = [1162:1215];
        ttrap = [1215:1322];
        tlopen3 = [1322:1378];
        trust4 = [1378:1557];
    elseif i==3
        %Subject3(4)
        run data4.m
        emp = empssubject3;
        temp = tempssubject3;
        spire = spiressubject3;
elseif i==4

%Subject4(4)
run data4.m
emp = empssubject4;
temp = tempssubject4;
spire = spiressubject4;

elseif i==5
%Subject4(5)
run data5.m
emp = empssubject4;
temp = tempssubject4;
spire = spiressubject4;

elseif i==6
%Subject2(5)
run data5.m
emp = empssubject2;
temp = tempssubject2;
spire = spiressubject2;

trust1 = [48:228];
tlopen1 = [228:527];
trust2 = [527:708];
tzitten = [708:1012];
trust3 = [1012:1188];
tlopen2 = [1188:1259];
ttrap = [1259:1363];
tlopen3 = [1363:1434];
trust4 = [1434:1592];
ttrap = [1264:1355];
tlopen3 = [1355:1411];
trust4 = [1411:1591];

    elseif i==7

%Subject3(5)
run data5.m
emp = empsubject3;
temp = tempsubject3;
spire = spiresubject3;

trust1 = [50:230];
tlopen1 = [230:534];
trust2 = [534:714];
tzitten = [714:1011];
trust3 = [1011:1190];
tlopen2 = [1190:1248];
ttrap = [1248:1348];
tlopen3 = [1348:1407];
trust4 = [1407:1589];

elseif i==8

%deze meting kon niet gedaan worden, is dus ook niet gebruikt in de
%grafieken
%Subject1(5)
run data4.m
emp = empsubject1;
temp = tempsubject1;
spire = spiresubject1

trust1 = [82:262];
tlopen1 = [262:567];
trust2 = [567:742];
tzitten = [742:1042];
trust3 = [1042:1224];
tlopen2 = [1224:1252];
ttrap = [1252:1362];
tlopen3 = [1362:1392];
trust4 = [1392:1582];

end

t=emp(1,1:end);
HR = emp(2,1:end);

figure(1)
plot(t(trust1),HR(trust1), 'gr');
hold on
plot(t(tlopen1),HR(tlopen1), 'b');
plot(t(trust2),HR(trust2), 'gr');
plot(t(tzitten),HR(tzitten), 'y');
plot(t(trust3),HR(trust3), 'gr');
plot(t(tlopen2),HR(tlopen2), 'b');
plot(t(ttrap),HR(ttrap), 'r');
plot(t(tlopen3),HR(tlopen3), 'b');
plot(t(trust4),HR(trust4), 'gr');
hold off
```matlab
title('change in heart rate')
xlabel('time(s)')
ylabel('heart rate(beats/min)')
hold on

figure(2)
subplot(2,1,1);
plot(t,HR);
title('MEWS score heart rate')

x= [0 1600];
y1= [100.5 100.5];
y2= [110.5 110.5];
y3= [129.5 129.5];
y4= [50.5 50.5];
y5= [40.5 40.5];
for ii=1:length(HR)
    if HR(ii)>= 129.5
        c= 'r';
    elseif HR(ii) >= 110.5
        c= [1 .5 0];
    elseif HR(ii) >= 100.5
        c= 'y';
    elseif HR(ii) >=50.5
        c= 'gr';
    elseif HR(ii) >=40.5
        c= 'y';
    else
        c= [1 .5 0];
    end

figure(4)
subplot(2,1,1)
plot(t(ii),HR(ii),'*', 'color',c)
title('MEWS heart rate')
hold on
line(x,y1, 'Colour', 'y')
line(x,y2, 'Colour', [1 0.5 0])
line(x,y3, 'Color', 'r')
line(x,y4, 'Color', 'y')
line(x,y5, 'Color', [1 .5 0])
xlabel('time(s)');
ylabel('heart rate (beats/min)')
end

%% temperatuur

figure(2)
plot(t(1:3),temp2(1:3), 'gr');
hold on
plot(t(3:4),temp2(3:4), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(4:8),temp2(4:8), 'b'); % open1
plot(t(8:9),temp2(8:9), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(9:11),temp2(9:11), 'gr'); % rust2

end
```
```matlab
% change in body temperature
plot(t(11:12), temp2(11:12), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(12:16), temp2(12:16), 'y'); % zitten
plot(t(16:17), temp2(16:17), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(17:19), temp2(17:19), 'gr'); % rust3
plot(t(19:20), temp2(19:20), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(20:22), temp2(20:22), 'r'); % trap
plot(t(22:23), temp2(22:23), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(23:25), temp2(23:25), 'b'); % rust4

title('change in body temperature')
xlabel('time(s)')
ylabel('temperature(degrees Celsius)')

% ADEMFREQUENTIE

t = spire(1,1:end);
RR= spire(2,1:end);
figure(3)

plot(t(1:3), RR(1:3), 'gr'); % overgang tussen handelingen
hold on
plot(t(3:4), RR(3:4), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(4:8), RR(4:8), 'b'); % lopen1
plot(t(8:9), RR(8:9), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(9:11), RR(9:11), 'gr'); % rust2
plot(t(11:12), RR(11:12), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(12:16), RR(12:16), 'y'); % zitten
plot(t(16:17), RR(16:17), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(17:19), RR(17:19), 'gr'); % rust3
plot(t(19:20), RR(19:20), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(20:22), RR(20:22), 'r'); % trap
plot(t(22:23), RR(22:23), 'color', [1 .5 0]); % overgang tussen handelingen
plot(t(23:25), RR(23:25), 'b'); % rust4

title('change in respiratory rate')
xlabel('time(s)')
ylabel('respiratory rate(breaths/min)')
hold on
xx= [0 1600];
yy1= [29.5 29.5];
yy2= [20.5 20.5];
yy3= [14.5 14.5];
yy4= [9 9];

for ii=1:length(RR)
    if RR(ii)>= 29.5
        cc = 'r';
    elseif RR(ii) >= 20.5
        cc = [1 .5 0];
    elseif RR(ii) >= 14.5
        cc = 'y';
    elseif RR(ii) >=9
        cc = 'gr';
    else
        cc = [1 .5 0];
    end
end
figure(4)
subplot(2,1,2)
plot(t(ii),RR(ii), '*', 'color', cc)
title('MEWS respiratory rate')
```

hold on
line(xx,yy1, 'Color', 'r')
line(xx,yy2, 'Color', [1 0.5 0])
line(xx,yy3, 'Color', 'y')
line(xx,yy4, 'Color', [1 0.5 0])
xlabel('time(s)')
ylabel('respiratory rate (breaths/min)')
end

%% MEWS
MEWSHR = zeros(1,length(RR)*59);
MEWSHR(HR>=100.5)=1;
MEWSHR(HR>=110.5)=2;
MEWSHR(HR>=129.5)=3;
MEWSHR(HR<=50.5)=1;
MEWSHR(HR<=40.5)=2;

MEWSHR = MEWSHR(1:length(RR)*59);

interRR= interp(RR,(length(RR)*59)/length(RR));
MEWSRR = zeros(1,length(RR)*59);
MEWSRR(interRR>=14.5) = 1;
MEWSRR(interRR>=20.5) = 2;
MEWSRR(interRR>=29.5) = 3;
MEWSRR(interRR<=9) = 2;

MEWS = MEWSHR + MEWSRR;

t = emp(1,1:length(RR)*59);
x= [0 1500];
y= [3 3];
figure(6)
plot(t,MEWS)
title('MEWS')
xlabel('time(s)')
ylabel('MEWS-score')
hold on
line(x,y,'Color', 'gr')

%tabellen maximale waardes
T1 = max(HR(trust1));
T2 = max(HR(tlopen1));
T3 = max(HR(trust2));
T4 = max(HR(tzitten));
T5 = max(HR(trust3));
T6 = max(HR(tlopen2));
T7 = max(HR(ttrap));
T8 = max(HR(tlopen3));
T9 = max(HR(trust4));

TT = [T1 T2 T3 T4 T5 T6 T7 T8 T9];
tabelmaxHR(i,1:9)= TT;

T1 = min(HR(trust1));
T2 = min(HR(tlopen1));
T3 = min(HR(trust2));
T4 = min(HR(tzitten));
T5 = min(HR(trust3));
T6 = min(HR(tlopen2));
T7 = min(HR(ttrap));
T8 = min(HR(tlopen3));
T9 = min(HR(trust4));

TT = [T1 T2 T3 T4 T5 T6 T7 T8 T9];

tabelminHR(i,1:9) = TT;

range = 60;
T1 = mean(HR(trust1(30):(tlopen1(1)-range/2)));
T2 = mean(HR(tlopen1(30):(trust2(1)-range/2)));
T3 = mean(HR(trust2(30):(tzitten(1)-range/2)));
T4 = mean(HR(tzitten(30):(trust3(1)-range/2)));
T5 = mean(HR(trust3(30):(tlopen2(1)-range/2)));
T6 = mean(HR(tlopen2(30):(ttrap(1)-range/2)));
T7 = mean(HR(ttrap(30):(tlopen3(1)-range/2)));
T8 = mean(HR(tlopen3(30):(trust4(1)-range/2)));
T9 = mean(HR(trust4(30):(trust4(end))));

TT = [T1 T2 T3 T4 T5 T6 T7 T8 T9];
tabelgemiddeld(i,1:9) = TT;
TTperc = ((TT-T1)./T1).*100;
Tperc(i,1:9) = TTperc;
toc
end

tabelmaxHR
tabelminHR
tabelgemiddeld(8,1:9)=[mean(tabelgemiddeld(1:7,1)) mean(tabelgemiddeld(1:7,2))...mean(tabelgemiddeld(1:7,3)) mean(tabelgemiddeld(1:7,4))...mean(tabelgemiddeld(1:7,5)) mean(tabelgemiddeld(1:7,6))...mean(tabelgemiddeld(1:7,7)) mean(tabelgemiddeld(1:7,8))...mean(tabelgemiddeld(1:7,9))];
tabelgemiddeld
Tperc
toc